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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,734	STEINER ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/21/03*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claims 33-42 are pending.

Specification

The abstract of the disclosure is objected to because the abstract is too long. **Correction is required.** See MPEP § 608.01(b). The current abstract consists of approximately 230 words. Abstracts are limited to a length of 150 words. See MPEP §608.01(f):

> (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure **as a whole in a single paragraph of 150 words or less** commencing on a separate sheet following the claims. In an international application, which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33, 34, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Feldstein et al. (U.S. Patent No. 5,352,461).

The Applicant recites a method of delivering insulin, comprising administration of diketopiperazine microparticles complexed to insulin, wherein the diketopiperazine is selected from the group consisting of fumaryl, succinyl, malelyl, and glutaryl diketopiperazine.

Feldstein discloses drug delivery systems based on the formation of **diketopiperazine** (or analogs) **microparticles**, wherein the microparticles are formed in the presence of the drug to be delivered, for example, **insulin** or heparin (abstract and claims 1-7).

Feldstein discloses in Example 2 a method for the suppression of blood glucose by oral administration of insulin, wherein porcine insulin was **encapsulated in a succinyl diketopiperazine**. The pharmaceutical composition was administered to nine male rats. The results of this experiment, depicted in Figure 2a, demonstrated that the diketopiperazine-encapsulated insulin produced a marked fall in blood glucose levels, when administered orally, whereas oral administration of unencapsulated insulin showed no pharmacological effect. The term "complexed" is understood to read on covalent and non-covalent interactions between the diketopiperazine and insulin, including encapsulation.

Claims 33-35 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Steiner et al. (U.S. Patent No. 5,503,852).

The Applicant recites a method of delivering insulin, comprising administration of diketopiperazine microparticles complexed to insulin, wherein the diketopiperazine is selected from the group consisting of fumaryl, succinyl, malelyl, and glutaryl diketopiperazine.

Steiner discloses drug delivery systems based on the formation of **diketopiperazine** (or analogs) **microparticles**, wherein the microparticles are formed in the presence of the drug to be delivered, including **insulin**. It is noted that **glutaryl, fumaryl, and malelyl diketopiperazines** are explicitly recited Steiner's claim 4 and encompassed by the structure of the diketopiperazines depicted in column 5, lines 35-50 as well as claim 1 (abstract and claims 1-4 and 17). Steiner's claim 17 recites a method of administration (i.e. delivery) of biologically agent, including active proteins and peptides, in combination with microparticles formed of diketopiperazines.

Steiner discloses in Example 3 a method for the suppression of blood glucose by oral administration of insulin, wherein porcine insulin was **encapsulated in a fumaryl diketopiperazine**. The pharmaceutical composition was administered to 3 male rats. The results of this experiment, depicted in Figure 2a, demonstrated that the diketopiperazine-encapsulated insulin produced a marked fall in blood glucose levels, when administered orally, whereas oral administration of unencapsulated insulin showed no pharmacological effect. The term "complexed" is understood to read on covalent and non-covalent interactions between the diketopiperazine and insulin, including encapsulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein (U.S. Patent No. 5,976,569) ("Milstein").

The Applicant claims a method of delivering insulin, comprising administration of diketopiperazine microparticles complexed to insulin, wherein the diketopiperazine is selected from the group consisting of fumaryl, succinyl, malelyl, and glutaryl diketopiperazine.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Milstein teaches **diketopiperazine delivery systems** (title and abstract) comprising (a) an active agent and either (b1) a carrier of at least (i) one amino acid and (ii) at least one diketopiperazine or (b2) at least one mono-N-substituted, di-N-substituted, or unsubstituted diketopiperazine (abstract). Milstein teaches that numerous agents are not amenable to oral administration, including biologically active peptides, such as calcitonin and **insulin** (col. 1, lines 38-42). The general chemical structure corresponding to the diketopiperazines taught by Milstein are disclosed from column 4, line 46 through column 5, line 37 (especially col. 4, line 46 to col. 5, line 6). Said chemical structure encompasses fumaryl, succinyl, malelyl, and glutaryl diketopiperazines. The active agents suitable for use in Milstein's invention are biologically active agents, particularly small peptides and hormones, including **insulin**. Milstein's compositions may comprise one or more active agents (col. 3, lines 10-35, especially col. 3, line 28). The delivery systems taught by Milstein are pharmacologically harmless, as are the **microspheres** prepared therefrom. The **microspheres containing an active agent** may be in the form of a matrix or **microcapsule**. In the matrix form, the active agent is distributed throughout the matrix of a system wherein the matrix forms a shell around a hollow center or wherein the matrix is a solid sphere. In the microcapsule form, a carrier forms a shell, which encapsulates the active agent either as a solid or a solution. In Examples 26-26A, Milstein teaches the oral administration (i.e. delivery) of insulin to anesthetized rats. Example 27 teaches the oral administration of interferon to rats. Both interferon and calcitonin are biologically active peptides and calcitonin is also a hormone.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Milstein does not anticipate claims 33-38 of the instant application; because insulin is one of many biologically active agents recited in the specification and is not exemplified. Milstein does not refer to diketopiperazine carriers.

Notwithstanding the aforementioned, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention to select insulin as the biologically active agent incorporated in Milstein's delivery systems, because like calcitonin, insulin is a biologically active proteinic hormone that is not amenable to oral administration. A skilled artisan would have been motivated to select insulin from Milstein's list of possible active agents, because it is a proteinic hormone that is not amenable to oral administration and the successful delivery of calcitonin was exemplified by Milstein in Example 26A. A skilled artisan would have had a reasonable expectation of success upon substitution of insulin for calcitonin as the active agent administered orally, using the prior art's delivery system, because, like calcitonin, insulin is a proteinic hormone not amenable to oral administration, when not delivered using Milstein's invention. Therefore, the Examiner concludes that claims 33-39 are *prima facie* obvious over the teachings of Milstein.

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al. (U.S. Patent No. 5,976,569) as applied to claims 33-39 above, and further in view of Edelman, S.V. (*Abstract only* of: "Type II Diabetes Mellitus," Advances in Internal Medicine, 1998, 43, pp 449-500).

The Applicant claims a method of delivering insulin, comprising administration of diketopiperazine microparticles complexed to insulin, wherein the diketopiperazine is selected from the group consisting of fumaryl, succinyl, malelyl, and glutaryl diketopiperazine; wherein the patient treated is a Type II diabetic; wherein the treatment occurs concurrently with or less than about 20 minutes of the patient eating a meal; and wherein the composition is provided in one or more unit doses of insulin, each dose equivalent to about 6 IU of insulin.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Milstein have been set forth above. Edelman teaches that when combination therapy fails, a split-mixed regimen using premixed 70/30 insulin pre-breakfast and pre-dinner can be effective in obese patients with Type II diabetes (abstract).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Millstein lacks the teaching of treating a patient with Type II diabetes, wherein treatment occurs concurrently with or less than 20 minutes prior to the patient eating a meal, and wherein the composition delivered to the patient has a dosage of 6 IU of insulin, provided in one or more unit doses.

It would have been obvious to a person of ordinary skill in the art to combine the teachings of Millstein and Edelman, because Edelman teaches that insulin may be used to treat obese patients with Type II diabetes, when combination therapy fails. A skilled artisan would have been further motivated to combine the teachings of Millstein and Edelman and would have

had a reasonable expectation of success upon combination, because Edelman teaches that the treatment of obese patients with insulin, when combination therapy fails, can be very effective. Regarding the concentration of insulin delivered upon administration, the amount of a specific ingredient (e.g. the dosage of an active agent) in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, and 10-14 of U.S. Patent No. 6,071,497 (USPN '497). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping and scope and mutually obvious. Both the cited claims of the instant application and those of UPSN '497 recite methods of delivering insulin, comprising the administration of diketopiperazine microparticles further comprising insulin. Both USPN '497 and the instant application recite a method wherein the composition is in the form of a dry powder (claim 39 of the instant application and claim 6 of USPN '497). Although the cited claims of USPN '497 do not recite that the insulin is complexed to the diketopiperazine, it would have been apparent that this associative interaction is a property of a composition comprising both a diketopiperazine and insulin. The cited claims of USPN '497 do not recite specific diketopiperazine derivatives, such as fumaryl diketopiperazine, however, the term "diketopiperazine" is understood to refer to a genus of compounds, which encompasses fumaryl diketopiperazine and other amidated diketopiperazines (e.g. succinyl, maleyl, glutaryl, etc.). Therefore, claims 33-39 are *prima facie* obvious over claims 1, 4-7, and 10-14 of U.S. Patent No. 6,071,497.

Claims 33-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7, and 10-12 of U.S. Patent No. 6,428,771 (USPN '771). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping and scope and mutually obvious. Both the cited claims of the instant application and those of UPSN '771 recite methods of

delivering insulin, comprising the administration of diketopiperazine microparticles further comprising insulin. Both USPN '771 and the instant application recite a method wherein the composition is in the form of a dry powder (claim 39 of the instant application and claims 6 and 12 of USPN '771). Although the cited claims of USPN '771 do not recite that the insulin is complexed to the diketopiperazine, it would have been apparent that this associative interaction is a property of a composition comprising both a diketopiperazine and insulin. The cited claims of USPN '771 do not recite specific diketopiperazine derivatives, such as fumaryl diketopiperazine, however, the term "diketopiperazine" is understood to refer to a genus of compounds, which encompasses fumaryl diketopiperazine and other amidated diketopiperazines (e.g. succinyl, maleyl, glutaryl, etc.). Therefore, claims 33-39 are *prima facie* obvious over claims 1, 4-7, and 10-12 of U.S. Patent No. 6,428,771.

Claims 33-35 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-12, 15-17, and 21-26 of U.S. Patent No. 6,444,226 (USPN '226). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping and scope and mutually obvious. Both the cited claims of the instant application and those of UPSN '226recite methods of delivering insulin, comprising the administration of diketopiperazine microparticles further comprising insulin. Both USPN '226and the instant application recite a method wherein the composition is in the form of a dry powder (claim 39 of the instant application and claims 6 and 12 of USPN '771). Both the cited claims of the instant application and those of USPN '226 recite that a peptide (e.g. insulin) is complexed to a diketopiperazine (e.g. fumaryl

diketopiperazine). The cited claims of USPN '226 recite fumaryl diketopiperazine. Therefore, claims 33-35 and 39 are *prima facie* obvious over claims 11-12, 15-17, and 21-26 of U.S. Patent No. 6,444,226.

Claims 33-35 and 40-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,652,885 (USPN '885). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping and scope and mutually obvious. Both the cited claims of the instant application and those of UPSN '885 recite methods of delivering insulin, comprising the administration of diketopiperazine microparticles complexed to monomeric or dimeric insulin, wherein the diketopiperazine is fumaryl diketopiperazine; the patient in need is a Type II diabetic; administration occurs concurrently with or less than 20 minutes prior to the patient eating a meal; the composition is provided in one or more unit doses of insulin, each dose equivalent to about 6 IU of insulin. The difference between the cited claims of the instant application and those of USPN '885 is that independent claim 33 of the instant application in addition to fumaryl diketopiperazine recites diketopiperazine derivatives selected from a group consisting of succinyl, malelyl, and glutaryl diketopiperazine. Therefore, claims 33-35 and 40-42 are *prima facie* obvious over claims 1-6 of U.S. Patent No. 6,652,885.

Claims 33-39 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-36 of copending Application No. 10/706,243 (copending '243). Although the conflicting claims are not

identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Both claims sets recite methods of delivering diketopiperazine microparticles selected from a group consisting of succinyl, glutaryl, malelyl, and fumaryl diketopiperazine, wherein the composition is administered to the lungs of a patient in need. Although the claims of copending '243 do not recite a composition in a dry powder form, it would have been obvious to a person of ordinary skill in the art at the time of the instant invention that a powder is a particulate composition, and would be rendered obvious by a composition comprising microparticles. Regarding the amount of insulin present in a given composition utilized in the practice of the method of both applications, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Therefore, claims 33-39 and 42 are *prima facie* obvious over claims 23-36 of copending application '243.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-39 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-10, 16-17, 23-

24, 26-30, and 36 of copending Application No. 11/210,710 (copending '710). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and are mutually obvious. Both claims recited methods of delivering a comprising a biologically active agent and a heterocyclic compound in the form of a dry powder to a patient in need of treatment. Formula 1 of the heterocyclic salts recited in claim 36 of copending '710, wherein E_1 and E_2 are N and R_1 and R_2 comprise at least one carboxylate functional group, encompasses the salt forms of the different diketopiperazine derivatives recited in the instant application. The pharmaceutical and therapeutic compositions recited in copending '710 comprising heterocyclic salts of formula 1 and hormones as the biologically active agent render a method of delivery of insulin comprising the step of administration obvious. It would have been apparent to a person of ordinary skill in the art at the time of the instant application that pharmaceutical and therapeutic compositions would be utilized in a method comprising the step of administration of said compositions to a patient in need thereof. Furthermore, it would have been obvious to the skilled artisan that insulin is a hormone. Therefore, 33-39 and 42 of the instant application are *prima facie* obvious over claims 1-5, 8-10, 16-17, 23-24, 26-30, and 36 of copending '710.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-35 and 40-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 17-23 of copending Application No. 11/329,686 (copending '686). Although the conflicting claims are

not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and are mutually obvious. Both claim sets recite methods of delivering insulin to a patient in need thereof. The term "exogenously administered" reads on the term "delivery." Both methods also recite the limitation that the patient is a Type II diabetic (claim 5 of copending '686 and claim 40 of the instant application). Claims 17-23 of copending '686 recite a method wherein the composition comprises a complex between a diketopiperazine (e.g. fumaryl diketopiperazine) and insulin. It would have been apparent to a skilled artisan that inhalation of the composition recited in the method claims of copending '686 would result in delivery of said composition to the lungs of a patient in need thereof. Therefore, claims 33-35 and 40-42 are *prima facie* obvious over claims 1-5 and 17-23 of copending Application No. 11/329,686 (copending '686).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 33-42 are rejected. The abstract is objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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